GLYPHOSATE HUMAN HEALTH AND MONARCH BRIEFING

October 21, 2015

Ecological Risk Assessment

- Terrestrial invertebrate Assessment and Monarchs
  - No toxicity data available for direct effects to monarchs
  - While acute adult contact and oral and semi-field honeybee toxicity data suggest toxicity from glyphosate exposure is low, the calculated EECs are greater than highest concentrations tested in honeybee toxicity tests. Additional testing may be requested.
    - Uncertainty with potential impact on survival, growth, and/or reproduction of honeybee larvae if exposed to residues (exposure in the larvae diet as a result of direct deposition or spray drift) *occur at an application rate up to roughly 3.8 lb a.e./A*.
    - Uncertainty with potential acute effects to adult honeybee at application rates >5.7 lb a.e./A.
  - Additional terrestrial invertebrate survival data (i.e., predatory mite) suggest potential direct effects up to 69 feet off-field

Ecological Risk Assessment

- Terrestrial Plant Toxicity including Milkweed
  - Milkweed: Reported toxicity values of 0.04 (0.03-0.07) & 0.126 lb a.e./A
  - Similar to most sensitive value from submitted plant toxicity studies and other open literature studies (0.074 lb a.e./A for cucumber).
  - Therefore, current toxicity data may be representative of potential adverse effects to common milkweed.
  - Distance off-site to be below toxicity thresholds, based on spray drift and varying application rates (0.38 to 8 lb a.e./A):
    - Aerial: ~30 to over 1000 ft
    - Ground: ~16 to over 250 ft

Risk Management Approach for Protecting the Monarch Butterfly

- EPA published "Risk Management Approach for Understanding and Identifying Protections for the Monarch Butterfly" on 6/24/15
- Comment period was extended from 30 days to 60 days
- Comment period closed 8/24/15
- EPA received approximately 41,000 comments on its monarch risk management document
- Most comments came from two mass mail campaigns
  - Center for Biological Diversity (about 6,000 comments from private citizens)
  - Food and Water Watch (about 35,000 comments from private citizens)

Monarch Comments

- Of the comments received, about 100 were substantive
  - Industry (ex. Crop Life America, Syngenta, Monsanto, RISE)
  - Grower groups (ex. CA Specialty Crops Council, National Corn Growers Association, American Soybean Association, American Sugar beet Growers Association, National Potato Council)
  - State Regulatory Departments (ex. Utah Dept of Ag and Food)
  - Environmental groups (ex. NRDC, Center for Biological Diversity, IA Monarch Conservation Consortium)
  - USDA's Office of Pest Management and Policy
  - Others (ex. National Association of Landscape Professionals, Public Policy National Association of State Depts of Agriculture, independent scientists)

Scope of Comments

- Industry and grower groups support a balanced approach for monarch protection and weed management
- Industry and grower groups want input on any proposed risk mitigation targeted for monarchs and milkweed
- Environmental groups and the public do not think we are doing enough
- The public is fond of the monarch butterfly, perceives large risk from use of pesticides, and doesn't understand our process/policy for pesticide risk management
- Some thoughtful suggestions/ideas for monarch protection
- Studies/data from a couple scientists

Monarchs–Proposed Next Steps

- Review/Analyze Comments
- Formulate Options for a Plan for Monarch Protection
- Considerations for monarch protection into registration review risk management decisions
  - Continue to work with stakeholders
  - Consider best management practices
  - Consider drift reduction measures on herbicide labels
  - Monarch protection measures expected to be in line with EPA's larger pollinator protection goals

Preliminary Human Health Risk Assessment

- HED Risk assessment (includes all uses and current policies)
  - Chronic Dietary: 13% cPAD (1-2 yr olds) and 5% (US POP); unrefined
  - Aggregate (LOC = 100): 460 (1-2 yr olds) and 2300 (adults)
- AMPA discussion (glyphosate metabolite)
  - Not included in US tolerances or Codex MRLs
    - Limited data shows glyphosate PODs are protective as AMPA less toxic
    - AMPA tox data shows xxxx
  - Included in PMRA MRLs
  - PMRA view of AMPA:
- Spray Drift assessment
  - Registered turf use protective of potential spray drift exposures
- Volatilization assessment
  - Glyphosate not included in volatilization screen because it is not volatile ~~no hazard seen in route specific inhalation study~~

Preliminary Human Health Risk Assessment

- Breast milk analysis
  - BEAD analyzed human milk samples collected by the National Childrens' Study for residues of glyphosate and glyphosate metabolites *N*-acetyl-glyphosate and AMPA
  - Total of 39 samples from 39 mothers were analyzed using a fully validated LC/MS/MS which has a high level of specificity for the target analytes
  - No residues of glyphosate and its metabolites were detected at or above the LOD (glyphosate LOD = 3.3 ppb; *N*-acetyl-glyphosate and AMPA LOD = 10 ppb).
  - To ensure results are not due to impacts of storage, a frozen storage stability study is being conducted with control milk samples fortified with glyphosate, *N*-acetyl-glyphosate, and AMPA.
    - Fortified samples will be analyzed after 4, 8, and 12 months of storage (the 4-month samples have been analyzed with no degradation noted).
    - Based on milk data associated with the livestock feeding studies, anticipate stability of glyphosate, N-acetyl-glyphosate, and AMPA will be demonstrated out to 12 months.
- Washington State University breast milk study and results

Preliminary Human Health Risk Assessment

- Open Literature Study Review
  - 67 studies reviewed in conjunction with PMRA (primary reviewer) from 62 individual references
    - Overall, most studies were deemed “unacceptable” for use in risk assessment based on the agency literature study guidance
    - No studies quantitatively impact the hazard characterization or human health risk assessment
  - Since review with PMRA (2012), an additional 399 studies have been reviewed
    - Search of PubMed from Jan 2012 to Oct 2015 = 392 journal articles
    - Cross-referenced list with studies submitted by various NGOs and added another 7 studies
    - Utilized systematic review process to determine whether articles were relevant to human health risk assessment
    - No studies quantitatively impact the hazard characterization or human health risk assessment

Preliminary Human Health Risk Assessment

- Tier II Incident and Epidemiology Report
  - 55 epidemiology studies examining potential cancer and non-cancer, chronic health effects
    - Overall HED could not conclude glyphosate plays a role in any of the health outcomes studied across the available epidemiologic data
    - PMRA relying on HED report
  - Only one study reflected an *a priori* research interest in the potential role of glyphosate and chronic disease outcomes
  - Several (case control) studies did show non-statistically significant increase in non-Hodgkins lymphoma associated with glyphosate exposure
    - Limitations of study design and exposure assessment methods restrict the ability of these studies to inform causal inference
  - Glyphosate was part of the Agricultural Health Study
  - ~~In 2014 IARC members published report using subset (6) of NHL studies; finding a positive association between glyphosate and NHL~~
    - ~~Despite evidence, review indicates the need for investigations of a larger variety of pesticides in more geographic areas~~

Glyphosate—EDSP Tier I Screening Results

- No evidence of interaction with estrogen, androgen, and thyroid signaling pathways
- Glyphosate was not identified for Tier 2 screening

Human Health Risk Assessment

- Cancer Reevaluation

Glyphosate: Communications Strategy

- Regional call – Set up day prior to announcement; GISB and CSB participating
- Stakeholder calls – Made day of announcement; PRD and CSB participating
  - USDA
  - DHHS
  - PMRA
- Docket materials – Posted day of announcement by PRD
- Other Web content – Posted day of announcement by ITRMD Web team
  - Glyphosate fact sheet
  - External Q&A document
- OPP Update – Sent day of announcement by CSB; posted to Web by ITRMD Web team

Items to be Published in Docket

- Updated Screening Level Usage Analysis (SLUA)
- Glyphosate Resistance Management Recommendations
- Preliminary Ecological Risk Assessment
- Preliminary Human Health Risk Assessment
- Glyphosate: Report of the Cancer Assessment Review Committee
- Glyphosate—Literature Search Review
- Analysis of Human Milk for Incurred Residues of Glyphosate and its Metabolites
- Glyphosate: Tier II Incident Report
- Joint Glyphosate Task Force's Use Data Matrix for Glyphosate

Questions?